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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/777,304 | 02/12/2004 | Kai Donsbach | I/1268b-1-C1 | 5299 |

28501 7590 09/06/2005

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EXAMINER

STOCKTON, LAURA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1626

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/777,304 | DONSBACH ET AL. | |
| | Examiner | Art Unit | |
| | Laura L. Stockton, Ph.D. | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 13, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-3 are pending in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGasparo et al. {WO 97/31634} and Huel et al. {U.S. Pat. 5,594,003}, each taken alone or in combination with each other.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim the hydrochloric acid, hydrobromic acid, toluenesulphonic acid and the methanesulphonic acid addition salts of Telmisartan. DeGasparo et al.

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(pages 5, 8 and 12) and Huel et al. (compound D in column 52, lines 47-49; Example 9 in column 60; column 51, lines 1-7; and column 56, lines 23-43) each teach the hydrochloric acid, hydrobromic acid, toluenesulphonic acid and the methanesulphonic acid addition salts of Telmisartan.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the instant claimed compounds and the compounds in the prior art is that the prior art generically describes the various salts of Telmisartan.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar

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compounds would possess similar activity (e.g., angiotensin antagonists).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, arteriosclerosis. Since each of DeGasparo et al. and Huel et al. teach the salts of Telmisartan and that Telmisartan is useful in treating, for example, arteriosclerosis, the combination of the prior art would also teach the instant claimed invention. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicants' arguments filed June 13, 2005 have been fully considered. Applicants argue that: (1) DeGasparo

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et al. and Haul et al. assume that a number of the disclosed compounds will be able to form acid addition salts; (2) Example 9 in DeGasparo et al. is the compound telmisartan however no acid addition salt is disclosed; (3) DeGasparo et al. do not specifically teach which of the disclosed AT₁ receptor antagonists fulfill the criteria of possessing a basic center which can form acid addition salts; and (4) since Telmisartan is an AT₁ receptor antagonist which carries an acidic carboxy group, neither from the teaching of Haul et al. nor from the teaching of Haul et al. in combination with DeGasparo et al. is it possible for persons skilled in the art to determine whether telmisartan is able to form acid addition salts as disclosed and taught in the instant application.

All of Applicants' arguments have been considered but have not been found persuasive. Applicants claim the hydrochloric acid, hydrobromic acid, toluenesulphonic acid and the methanesulphonic acid

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addition salts of Telmisartan. DeGasparo et al. (page 5) and Huel et al. (column 51, lines 1-7) each teach that Telmisartan can be in the form of a pharmaceutically acceptable salt. Further, Huel et al. disclose carboxylic acid containing compounds in a pharmaceutically acceptable salt form. See compound K in column 53, lines 1-3; and especially compound BB in column 53, lines 54-57. It would appear that Applicants are arguing that if a 35 USC § 102 rejection cannot be made, than a rejection under 35 USC § 103 should not be made. This is not the basis or rationale used for determining an obviousness-type rejection. Absent a showing of unobvious, unexpected and beneficial results, the instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

August 23, 2005